

May 28, 2001

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Kimberly Topper
Center for Drug Evaluation and Research (HFD-21)
Food and Drug Administration
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Dear Ms. Topper:

I am writing this letter to alert the FDA to the importance of short-onset, long-acting narcotics available for the treatment of non-cancer pain.

I am a board certified adult medical oncologist and hematologist. I am interested in good care and appropriate pain control. Recently, I provided care for a man with hairy cell leukemia. This gentleman is in complete remission. He is a government employee, at a very high executive level. While working at his home he fell and injured some ribs. He spoke with his primary care physician who prescribed Percocet (5/500) in addition to ibuprofen. The oxycodone/APAP provided minimal benefit that lasted for 2 – 3 hours after each dose. With this regimen he could not sleep adequately and he was concerned about whether he injured his spleen. He had difficulty with work and had limited ability to ventilate due to pain.

I saw him, evaluated him, and obtained x-rays. These x-rays confirmed that he fractured 3 ribs. He was otherwise well. We discussed his pain control and I suggested that he take Oxycontin® 10 mg PO, 1-2 tabs *bid* and at least at *hs*. I dispensed #30 tablets. He took these and called a few days later. He noted marked benefit from 20 mg. He had some persistent pain, but he was able to sleep at night and work during the day. A few weeks later he called and requested a second prescription, which I ordered.

It is now 2 months since the injury. He notes that he could not think about anything else but the pain during the time before the Oxycontin®. He was able sleep and work with the Oxycontin®. He was able to achieve REM sleep with the oxycontin, but was awoken every 2-3 hours with the pain when he only had Percocet®.

Oxycontin® is safe and effective for cancer pain and certain non-cancer pain. Please do not limit the availability of Oxycontin®. This is an important drug. Would it be fair to my patients with cancer-related pain and non cancer-related pain to limit this drug? NO. Please advocate for good care of patients.

Sincerely,

A handwritten signature in black ink, appearing to read "David Shepro". The signature is fluid and cursive, with the first name "David" and last name "Shepro" clearly distinguishable.

David Shepro, MD

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